

**Notice of Allowability**

Application No.

10/661,750

Examiner

ALEX NOGUEROLA

Applicant(s)

TSENG ET AL.

Art Unit

1753

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/11/2003 and 6/30/2006.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 6/30/2006
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

**DETAILED ACTION**

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrew Chu on February 28, 2007.

The application has been amended as follows:

- a) Claim 1, line 4: "channel" has been replaced with -- channels --;
- b) Claim 1, line 4: the second occurrence of "the" has been replaced with -- each --;
- c) Claim 2, line 3: the second occurrence of "the" has been replaced with -- each --;

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d) Claim 8, line 2: between "is" and "a" the following has been inserted

-- made of --

e) Claim 13, line 2: between "on" and the first occurrence of "the" the following

has been inserted -- on the substrate to be --;

f) Claim 19, line 2: "18," has been replaced with -- 17, --;

g) Claim 20, line 2: "19," has been replaced with -- 18, --;

h) Claim 20, line 2: the second occurrence of "the" has been replaced with

-- each --;

i) Claim 18 has been renumbered as claim 17;

g) Claim 19 has been renumbered as claim 18; and

h) Claim 20 has been renumbered as claim 19.

***Allowable Subject Matter***

2. Claims 1-19 are allowed.

3. The following is an examiner's statement of reasons for allowance:

There is one independent claim, claim 1. It requires

“ a substrate;

at least two H-shaped micro channels formed on the substrate, each H-shaped micro channel including:

(a) two main channels; and

(b) at least one sub-channel, wherein two ends of the sub-channel are separately connected to the two main channels;

a reagent filled in the at least one sub-channel; and

a sample diversion layer having at least one sample channel with at least one sample entrance placed above the at least one sub-channel.”

US 6,709,559 B2 (“Sundberg et al.”) discloses a microfluidic device with network microchannels, comprising:

a substrate (16);

at least one H-shaped micro channel formed on the substrate, each H-shaped micro channel including:

(a) two main channels (76,88); and

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(b) at least one sub-channel (78) , wherein two ends of the sub-channel are separately connected to the two main channels; and  
a sample layer (32) with at least one sample entrance (34) placed above the at least one sub-channel.

See the abstract and Figure 7. Sundberg et al. does not , however, provide a reagent in the at least one sub-channel. The sub-channels are for electrophoretic separation and preferably contain a separation solution containing a polymer. See col. 09:39-42. Sundberg et al. also only forms one H-shaped micro channel on the substrate. Additionally, Sundberg et al. does not provide at least one sample channel in the sample layer. The sample layer comprises either only an array of through-hole ports (34) for wicking sample that is in the form of drops on pins into the device or a single blind reservoir (66) into which a drop of sample is applied. See col. 05:39-67 and col. 08:47-60. So, also, the sample layer is not a sample diversion layer as sample is not diverted in this layer along a sample channel, but directly applied to the H-shaped microchannel. Sundberg et al. teaches away from having a sample channel in the sample layer so that is a sample diversion layer because as noted above Sundberg et al. is especially configured so that individual drops of samples on pins can be applied to the device.

US 2003/0003026 A1 ("Parce et al.") discloses a microfluidic device with network microchannels, comprising:

a substrate (14);

at least one H-shaped micro channel formed on the substrate, each H-shaped micro channel including:

- (a) two main channels (16 in Figure 1 or "linking channels" in Figure 9A); and
- (b) at least one sub-channel (unlabeled channels between main channels 16 in Figure 1 or "separation channels in Figure 9A), wherein two ends of the sub-channel are separately connected to the two main channels; and

a sample layer (18) with at least one sample entrance (24) placed above the at least one sub-channel.

See the abstract and Figures 1 and 9A. Parce et al. only forms one H-shaped micro channel on the substrate. Parce et al. does not provide a reagent in the at least one sub-channel. Additionally, Parce et al. does not provide at least one sample channel in the sample layer. The sample layer comprises a plurality of holes (24) for access to the ends of the channels. So, also, the sample layer is not a sample diversion layer as sample is not diverted in this layer along a sample channel, but directly applied to the H-shaped microchannel.

US 6,974,526 B2 ("Lee et al. ") discloses a microfluidic device with network microchannels, comprising:

- a substrate (C);
- at least two micro channels (2) formed on the substrate; and

a sample diversion layer (A) having at least one sample channel (3) with at least one sample entrance (5,6) placed above the at least one sub-channel.

See Figure 10. However, the at least two micro channels (2) formed on the substrate are not H-shaped channels as claimed, but "I" shaped microchannels. Also, even if the lower channel array (4) is construed as H-shaped, with microchannels 2 being sub-channels, there is no reagent filled in at least one sub-channel. Lee teaches away from this limitation. Channels 2 are to be used for the second dimension separation of proteins in an electrophoretic 2-D protein separation. In the first dimension of the 2-D separation the proteins are isoelectrically focused and then reacted (incubated) with SDS and/or dye, for example, in the at least one sample channel (3) in the sample diversion layer; that is, reaction of sample with reagent is to occur in the at least one sample channel. Channels 2 are for size-based separation of the protein fractions resulting from the separation in the at least one sample channel. See col. 08:44 – col. 09:04. Membrane B, which is between the at least one sample channel and the sub-channels, is implicitly likened to a microfilter that allows focused proteins through. See col. 08:06-15 and col. 08:30-37.

US 6,638,404 ("Terashima et al. ") discloses a microfluidic device with network microchannels, comprising:

a substrate (12);

at least two micro channels (grooves shown but not labeled in the substrate in Figure 5) formed on the substrate;

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a reagent (11 – ion selective membrane in the electrode) filled in the at least one sub-channel; and

a sample diversion layer (16) having at least one sample channel (17) with at least one sample entrance (20, 14) placed above the at least one sub-channel.

See the abstract; Figure 5; col. 04:41-61; and col. 05:36 – col. 06:11. However, the at least two micro channels (grooves shown but not labeled in the substrate in Figure 5) formed on the substrate are not H-shaped channels as claimed, but “I” shaped microchannels. There is no subchannel formed on the substrate “wherein two ends of the sub-channel are separately connected to the two main channels.”

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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